JUN 19 2003

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VI. 510(k) Summary of Safety and Effectiveness Information

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the safety and effectiveness information upon which substantial equivalence determination is based follows:

A. Submitter Information:

Applicant:	Bard Peripheral Vascular, a division of C.R. Bard, Inc. 1625 West 3rd Street Tempe, Arizona 85280
Phone:	480-303-2752
Fax:	480-449-2546
Contact:	Aymee R. Berry, Associate Manager, Regulatory Affairs

B. Device Name:

Trade Name:	FLUENCY™ Tracheobronchial Stent Graft
Common or Usual Name:	Tracheal Prosthesis
Classification Name:	Prosthesis, tracheal

C. Predicate Device Name(s):

WALLGRAFT™® Tracheobronchial Endoprosthesis
Boston Scientific

Bard LUMINEXX™ 7F Biliary Stent
C.R. Bard, Inc.

Bard memotherm® Covered Esophageal Stent
C.R. Bard, Inc.

VIABAHN™ Endoprosthesis
W.L. Gore & Associates, Inc.

D. Device Description:

The FLUENCY™ Tracheobronchial Stent Graft includes a self-expanding Nitinol Stent encapsulated with ePTFE pre-loaded on a flexible "pull-back" delivery system. It is a single use prosthetic device designed to maintain the patency of the tracheobronchial tree in patients with tracheobronchial strictures produced by malignant neoplasms or in benign strictures after all alternatives have been exhausted. Highly radiopaque Tantalum markers on the stent graft ends facilitate stent graft placement. The FLUENCY™ Tracheobronchial Stent Graft is available in various lengths and

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diameters. It is preloaded into various size delivery catheters, depending on the size of the stent graft.

E. Statement of Intended Use:

The FLUENCY™ Tracheobronchial Stent Graft is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms or in benign strictures after all alternative therapies have been exhausted.

F. Substantial Equivalence:

A variety of tests, assessments, and comparisons demonstrate that the FLUENCY™ Tracheobronchial Stent Graft is substantially equivalent to the following predicates in terms of composition, design, intended use, and performance attributes as noted below:

- The FLUENCY™ Stent Graft is substantially equivalent to the WALLGRAFT™ Endoprosthesis in indication for use, method of deployment, and *in-vitro* testing.

- The FLUENCY™ Stent Graft is substantially equivalent to the VIABAHN™ in both stent graft materials and indication for use.

In addition, safety and effectiveness of the FLUENCY™ Stent Graft is further supported by comparability to other legally marketed devices as follows:

- The FLUENCY™ Stent Graft and delivery system is comparable to the LUMINEXX™ 7F Biliary Stent Graft (Nitinol stent) and delivery system as previously demonstrated.

- The FLUENCY™ Stent Graft is comparable to the memotherm® Esophageal in covering and stent material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 2007

Bard Peripheral Vascular, Inc.
% Mr. Joshua Smale
Regulatory Affairs Specialist
1625 West 3rd Street
P.O. Box 1740
Tempe, Arizona 85280

Re: K031041
Trade/Device Name: FLUENCY™ Tracheobronchial Stent Graft
Regulation Number: 21 CFR 878.3720
Regulation Name: Tracheal prosthesis
Regulatory Class: II
Product Code: JCT
Dated: March 31, 2003
Received: April 7, 2003

Dear Mr. Smale:

This letter corrects our substantially equivalent letter of June 19, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

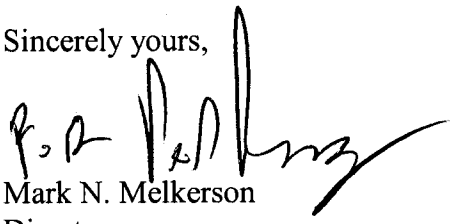
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K031041

Device Name: FLUENCY® Tracheobronchial Stent Graft

Indications for Use:

The FLUENCY® Tracheobronchial Stent Graft is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

Prescription Use__X___ AND/OR Over-The-Counter Use_____
(Part21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K031041